DIETARY COMPOSITION AND METHODS OF PREPARING

BACKGROUND OF THE INVENTION

1. The Invention

This invention relates to dietary compositions and to methods of preparing such diets. In a further aspect, this invention relates to dietary compositions which form stable emulsions, with water, of improved palatability. In a still further aspect this invention relates to low residue dietary compositions comprising peptides and/or amino acids, carbohydrates, lipids, and high amylose starch and the resulting liquid emulsions of such compositions with water and methods of preparing such compositions and emulsions.

2. The Prior Art

A number of synethetic or low residue diets have been provided by the prior art to provide the essential nutritional requirements of humans. Accordingly, such 20 diets contain amino acids, and/or an amino acid source such as protein, carbohydrates and lipids, plus an emulsifying agent and optional ingredients such as vitamins and minerals; note, for example, U.S. Pat. Nos. 3,697,287 and 3,777,930. Although such diets have 25 high nutritional value and could be used as a food replacement or supplement by normal human beings, they are primarily designed for pre- or post-operative patients or for patients with digestion problems. Two of the primary problems with respect to such diets are 30 palatability or aesthetic appeal and since they are consumed as aqueous emulsions, the inability of the compositions to form stable aqueous emulsions for a prolonged period of time, even with the assistance of emulsifying agents. The prior art compositions typically 35 form a two-phase liquid-liquid mixture, with water, one phase which is very rich in lipids and the other which is rich in amino acids and carbohydrates. Accordingly, when such emulsions are administered orally, the patient receives a substantially pure lipid layer which is 40 particularly unpalatable, and when tube-fed directly to the stomach, results in a non-uniform nutrient flow to

Accordingly, prior art low residue diet mixtures formulated with amino acids, or with peptides, are very low in fat because no method is available to keep the lipid material in suspension and any attempt to formulate these diets at fat levels greater than 1% (liquid wt.) results in a product that separated and had a greasy mouth feel. This is a very critical problem where the product is to be consumed orally. Also low fat diets require a greater volume of diet to be consumed because the carbohydrate that is used to replace the fat has only approximately one half the calorie density per gram.

In addition the amino acid based low residue diet of the prior art typically have a poor taste due to the amino acids themselves, and exert a very high osmotic load on the digestive tract of the individual consuming the diet, and are further very susceptible to non- 60 enzymatic browning.

Prior art formulas prepared with proteins are unacceptable for low residue diets because the proteins are not utilized efficiently by patients with certain gastrointestinal disorders. In contrast to the prior art protein 65 diet, the predigested proteins in the form of peptides utilized in this invention, are absorbed as efficiently by patients with gastrointestinal disorders as free amino

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acid diets and further the peptide diet offers the advantage of contributing less osmotic load to the diet. Also the functional ability of the peptides to stabilize the fat in the diet is greater than amino acids and further peptides have substantially less of an undesirable taste than amino acids.

Accordingly we have discovered both peptide based and amino acid based low residue dietary compositions which form aqueous emulsions of greatly improved stability and accordingly increased palatability and aesthetic appeal.

SUMMARY OF THE INVENTION

In summary the dry form, or storage form, of the dietary compositions, of the invention, comprise peptides and/or amino acids, carbohydrates, lipids, high amylose starch, and preferably a small amount of an emulsifying agent. In summary the liquid emulsion form, or administration form, of the composition, of the invention, comprise an aqueous emulsion of the dietary composition of the invention, having a stability against separation, at room temperature, of at least 12 hours, and typically 24 hours or longer, and a refrigeration stability at 34°F (1.1°C) of about 48 hours or longer, after hydration.

In summary, the processes of the invention for preparing our composition comprises heating and homogenizing an aqueous mixture of the components of the composition, then steam injecting and drying the homogenized mixture. Alternatively the steam injected mixture can be cooled and stored under mild refrigeration and, if desired, subsequently dried, or canned and stored and distributed as an aqueous emulsion.

The invention will be further described herein below.

FURTHER DESCRIPTION OF THE INVENTION AND PREFERRED EMBODIMENTS

The peptide compositions of the invention comprise about from 3 to 40 wt. % peptide mixture; about from 7.5 to 90 wt. % carbohydrates, about from 2 to 35 wt. % lipids and in addition to the carbohydrates about from 0.5 to 16 wt. % gelatinized high amylose starch; and a high amylose starch to lipid wt. ratio of at least 0.25; and about from 0.05 to 10% of a water-lipid emulsifying agent. In addition, the composition can also comprise small amounts of other components desired for the nutritional well being of the patient and aesthetic appeal of the product such as, for example, amino acids (or pharmaceutically acceptable salts thereof), vitamins, minerals, flavoring, coloring, antioxidants and the like. In terms of aqueous emulsion stability, best results are obtained, wherein the dry dietary composition comprises about from 4 to 22 dry wt. % peptide mixture, about from 22 to 84 wt. % car-55 bohydrates, about from 4 to 22 wt. % lipids and in addition to the carbohydrates about from 2 to 8 wt. % gelatinized high amylose starch; and about 0.4 to 2% of said water-lipid emulsifying agent and wherein the total free amino acid content of said composition is less than 1.5 %.

The peptide mixture used in our composition is a mixture of peptides in the proper relative quantities and ratio to provide all of the essential amino acid and such non-essential amino acids as are necessary to support all normal physiological functions dependent upon amino acids. Optionally the peptide mixture can also contain small amounts of amino acids either as by-products formed during the preparation of the pep-